AUG 2 0 2003

K 032283

# 510(k) Summary
# For
# Designs for Vision, Inc.
# Designs for Vision Fiberoptic Light

## 1. SPONSOR

Designs for Vision, Inc.
760 Koehler Avenue
Ronkonkoma, NY 11779

Contact Person: Gordon Perry
Telephone: (631) 585-3300

Date Prepared: July 23, 2003

## 2. DEVICE NAME

| | |
|---|---|
| Proprietary Name: | Designs for Vision Fiberoptic Light |
| Common/Usual Name: | Surgical Lights |
| Classification Name: | Surgical Lights/Routine Fiberoptic Lights |

## 3. PREDICATE DEVICES

| | |
|---|---|
| Designs for Vision Daylite Xenon Light Source | K013880 |
| Cuda Products Corporation M300 Light Source | K981962 |

## 4. DEVICE DESCRIPTION

The Designs for Vision Fiberoptic Light is composed of a high intensity light source, fiberoptic cables, and fiberoptic headsets. The Designs for Vision headsets have been marketed since the early 1970s with a long history of safe use in the surgical suite. The headsets are coaxial, bifurcated, or focusable designs.

The light source includes a chuck for fiberoptic cable attachment. The Light source provides a 150-watt power output and contains a continuous illumination level adjustment, which provides 3200 K color temperature light.

## 5. INTENDED USE

The Designs for Vision Fiberoptic Light is indicated for use in surgery and medical applications where high intensity illumination is required.

## 6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Designs for Vision Fiberoptic Light device has the same intended use as the predicate devices and similar technological characteristics. They all consist of Light Sources supplying fiberoptic illuminators with illumination for headlights.

## 7. PERFORMANCE TESTING

Testing has been performed which demonstrates the electrical safety and electromagnetic compatibility characteristics of the Designs for Vision Fiberoptic Light.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2003

Designs for Vision, Inc.
c/o Ms. Mary McNamara-Cullinane
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K032283
Trade/Device Name: Designs for Vision Fiberoptic Light
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GDB
Dated: July 23, 2003
Received: July 25, 2003

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032283

Device Name: Designs for Vision Fiberoptic Light

Indications for Use:

The Designs for Vision Fiberoptic Light is indicated for use in surgery and medical applications where high intensity illumination is required

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032283

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)